

I. Status of the Application and Claims

A. The Restriction of Claims 17-98

Claims 17-98 are pending in the application. The Office has made final the restriction and species election requirements set forth in the Office action mailed February 21, 2008. Office action, page 3. According to the Office, "Applicant has elected with traverse Group 1, product claims 17-51." *Id.*, page 2. In addition, the Office contends that "Applicant has elected species which are within the scope of claims 17-28, 31-34, and 36." *Id.* Claims 17-28, 31-34, and 36 have been examined and stand rejected. *Id.*, page 1. Claims 52-98 have been withdrawn as being directed to a nonelected invention. Claims 29-30, 35, and 37-51 have been withdrawn from consideration as not being drawn to elected species and in the absence of an allowable generic claim. *Id.* Respectfully, the Office's contentions are inconsistent with the written record of this application, as explained below.

Applicants filed an amendment on January 10, 2008, entering new claims 17-98 and cancelling all of the claims that had been under examination. An Office action was mailed on February 21, 2008, which addressed the new claims. In that paper, the Office objected to claims 17-51 under 35 U.S.C. § 132(a) as allegedly containing new matter. Office action mailed February 21, 2008, page 2. The Office stated that "[c]laims 17-51 will not be considered. . . ." *Id.*

The statement that the claims would not be considered was accurate because composition claims 17-51 were not addressed in the restriction requirement included in the February 21, 2008, Office action. The Office asserted that method claims 52-98 fell into two groups. Group I, comprising claims 52-77, was drawn to a first method utilizing

a medium comprising, among other things, "an antibiotic, wherein the antibiotic is cefoxitin, cefmetazole, or moxalactam." See, for example, claim 52. Group II, comprising claims 78-98, was drawn to a second method utilizing a medium comprising, among other things, "an antibiotic, wherein the antibiotic is flomoxef." See, for example, claim 78. The Office also imposed a multi-component species election requirement. Office action, mailed February 28, 2008, pages 5-8. In addition, the Office stated that claims 52 and 76 are generic. *Id.*, page 7. To summarize, composition claims 17-51 were not subject to either the restriction or the species election requirements as they were not considered. And method claims 52-98 were restricted into two groups based on the antibiotics included in the medium used in the methods.

Before responding Applicants had a telephonic interview with the Examiner on March 13, 2008, seeking clarification of the species election requirement. See Interview Summary mailed March 25, 2008. On March 18, 2008, Applicants filed their response to the restriction and species election requirements.¹ Applicants elected Group I, method claims 52-77, with traverse. Response, page 4. Applicants also elected species as required, and identified claims 52-66, 68-72, and 74-77 as encompassing the elected species. *Id.*, page 6. In a footnote, Applicants indicated that "[u]nexaminated [composition] claims 17-28, 31-34, and 36 also encompass the elected species." *Id.*

Thus, contrary to the assertion in the pending Office action at page 2, Applicants have never "elected with traverse Group I, product claims 17-51." The Office had not restricted the claims into a group of composition claims [17-51] and a group of method

¹ Applicants also submitted relevant evidence and argued for withdrawal of the new matter objection. The Office has withdrawn that objection. Office action mailed June 13, 2008, page 2.

claims [52-98]. Nor have Applicants "elected species which are within the scope of claims 17-28, 31-34, and 36. Instead, Applicants elected species encompassing method claims 52-66, 68-72, and 74-77.

Given the ambiguity in the written record as to exactly how the Office is restricting the claims, and the potential impact on Applicants rights, for example, rights provided under 35 U.S.C. § 121, Applicants respectfully ask the Office to clearly set forth the restriction requirement and how it applies to claims 17-98. For example, has the Office made final the restriction and species election requirements set forth in the Office action mailed February 28, 2008? Or has the Office maintained that restriction and species election requirements, and imposed an additional restriction between groups directed to compositions [claims 17-51] and methods [claims 52-98], which is now final, despite the fact Applicants have never been provided an opportunity to traverse it? Clarification is required.

Regardless of the source of the confusion, composition claims 17-28, 31-34, and 36 have received an examination on the merits. Although Applicants have filed on this date a petition seeking withdrawal of the restriction requirement [as they understand it], they consent to the continued examination of these claims despite the fact that they have not been formally elected. Further, Applicants believe that claim 17 is generic. Consistent with M.P.E.P. § 809.02(a), in the event that claim 17 is found patentable, Applicants request consideration of claims in the application directed to the non-elected species, that is, claims 29, 30, 35, and 36.

In addition, Applicants request rejoinder and examination of method claims 52-66, 69-72, and 74-77 in the event the Office finds the composition claims allowable.

See M.P.E.P. § 821.04. These claims, which Applicants did elect to prosecute, are directed to the same elected species. Furthermore, if generic claim 52 is rejoined and found patentable, Applicants request consideration of claims in the application directed to the non-elected species, that is, claims 67, 68, and 73.

B. IDS Filed January 10, 2008

Applicants acknowledge the initialed PTO/SB/08 forms returned with the Office action. Two of the references were "lined through," indicating they were not considered. No explanation for why the references were not considered has been provided. Applicants have filed an IDS with this Request that lists the two references, among other references being cited for the first time. Copies of the references are included in the event they were not received by the Office previously. Applicants request the Office to consider the references and indicate that consideration in the record.

C. Opposition to European Patent No. EP 1543147 B1

On January 10, 2008, Applicants submitted an IDS disclosing two oppositions, and references cited therein, to Applicants' related European Patent No EP 1543147 B1 ("European patent"). In the IDS submitted herewith, Applicants disclose for the Office's consideration additional submissions by the parties, references that have been newly cited, and a preliminary and non-binding opinion by the EPO's Opposition Division. Since the preliminary opinion is in French, Applicants have submitted a translation of the substantive discussion in the opinion.

As previously disclosed, oppositions to the European patent were filed by two parties. On April 15, 2008, the patentee filed a reply to the oppositions, wherein arguments and evidence were presented in rebuttal to the attacks on patentability

raised in the two oppositions. One of the opponents, Biorad Pasteur, filed on July 3, 2008, eight new references and a short response commenting on the Patentee's April submission. Based on the submissions of the parties to that date, the Opposition Division formulated its preliminary opinion on August 6, 2008.

In this non-binding opinion, the Opposition Division rejected arguments raised by the opponents attacking claims based on the adequacy of the description and novelty. See Translation, pages 4 and 5. The attacks based on lack of inventive step (obviousness) as formulated by the opponents were also not adopted. The Opposition Division, however, preliminarily concluded that a 2002 publication by Merlino et al. [submitted in the instant IDS] was the closest prior art under the standards applied in the EPO and concluded that the claims of the European patent lacked inventive step over the Merlino publication in view of the teaching provided in two articles by Felten, an article by Mougeot, and an article by Wertheim [all four articles were submitted in the January 10, 2008, IDS or already made of record].

On October 16, 2008, opponent bioMerieux filed a short letter with additional comments and some additional references and selected papers from the prosecution of the instant application. The Patentee, on the same date, filed a response to the non-binding opinion. In that response, the Patentee stated his disagreement with the Opposition Division not only with the identity of the closest prior art reference, but also with the patentability of the claims over the combination of references the Opposition Division contends render the claims unpatentable for lack of inventive step. The Office may consider the arguments made in the response, which is included with the IDS

submitted herewith. Oral argument in the opposition is scheduled for December 16, 2008.

II. The Claims Are Patentable Over the Cited References

A. The Claims Are Patentable Over the References of Record in the Office Action Mailed July 11, 2007, Further in View of U.S. Patent Nos. 5,989,853, 6,436,631, or 6,696,239 to Bochner or U.S. Patent No. 6,130,057 to Gosnell

The Office rejects claims 17-28, 31-34, and 36 under 35 U.S.C. § 103(a) as allegedly unpatentable "over the art of record as stated in the final rejection dated July 11, 2007," further in view of U.S. Patent Nos. 5,989,853, 6,436,631, or 6,696,239 to Bochner, or U.S. Patent No. 6,130,057 to Gosnell. Office action, page 4. Applicants traverse the rejection for the reasons of record as set forth in the Amendment filed on January 10, 2008, supplemented as follows.

According to the Office:

The claimed subject matter was considered to be prima facie obvious based on the art as submitted in A [Final Rejection] and B [Opposition]. However, the new instant claims are drawn to the same subject matter with an additional new limitation that the culture medium is a "gelled culture medium" which references lack this limitation.

The references of record do not anticipate the claimed inventions. In addition, the references alone or further in view of each other do not suggest or motivate one of ordinary skill in the art to employ a gelled culture medium which contains the specific claimed antibiotics.

However, [r]eferences to Bochner 5,898,853, 6,436,631 or 6,696,239 and Gosnell et al U.S. 6,130,057 teach gelled culture mediums[.]

Id., pages 4-5.

After addressing the asserted teachings of the Bochner and Gosnell references, the Office concludes that "[i]t would have been prima facie obvious to one of ordinary

skilled [*sic*] in the art to employ a gelled culture medium containing agar as taught by **Bochner** for the agar of **Gosnell et al** in combination with any one of a number of chromogens for the testing of *Staphylococcus* [*sic*] *aureus* in the presence of cefoxitin as taught by the references of A [prior Office action] of B [opposition]." *Id.*, page 7.

Applicants respectfully disagree.

Before addressing the substance of the rejection, Applicants note that the Office action mailed July 11, 2007, included the following combinations of references, which were applied to particular claims:

Merlino in view of Felten; claims 1, 10, and 11;

Merlino in view of Felten and Boggs; claims 1, and 10-12;

Merlino in view of Felten and Dorso; claims 1, and 10-12;

Merlino in view of Felten and Hanaki; claims 1, and 10-12;

Merlino in view of Felten and Rambach; claims 1, 3, 7, 8, and 10-12;

Merlino in view of Felten, Carricajo, and Pead; claims 1, 10, 11, and 14.

In their Amendment filed January 10, 2008, Applicants addressed each of these rejections with multiple arguments spanning pages 13-29 of the Amendment. The

Office has failed to address any of these arguments in the pending Office action.

Respectfully, that is improper. Relevant guidance is provided in M.P.E.P. § 707.07(f):

"Where the applicant traverses any rejection, the examiner should, if he or she repeats the rejection, take note of the applicant's argument and answer the substance of it."

Here the Office has not addressed the substance of the arguments of record. By failing to do so, it is impossible for the Applicants to advance the prosecution of this application

because they have no way of knowing why their arguments were not considered persuasive by the Office.

Furthermore, it is not clear from the pending Office action whether the Office is applying the references cited in the July 2007 Office action as a single collection combined with the references by Bochner or Gosnell, or in the same six groupings set forth in the July 2007 Office action combined with the references by Bochner or Gosnell, and if the latter, which claims are allegedly rendered obvious by which combination(s) of references. Again, the failure to provide this information prevents Applicants from providing a full and complete response to the pending rejections.

In an attempt to be responsive, Applicants will assume the Office is adding the teachings of Bochner or Gosnell to the six combinations of references listed above. In that case, Applicants traverse for the reasons of record and incorporate by reference their arguments in reply to each of the six combinations as set forth in the January 10, 2008 Amendment. In making the instant rejection(s), the Office appears to believe that Applicants have argued the claims are distinguishable over the cited combinations of references on the basis of their amendment to recite that the culture medium is "gelled." Thus, in the pending action the Office cites to Bochner and Gosnell as teaching the use of gelled culture media and combines that teaching with the references of record to find the claims obvious. Office action, page 5.

Applicants, however, have not argued their claims are distinguishable over the references cited in the July 2007 Office action solely because they recite a "gelled culture medium." Applicants cannot make that argument. The use of gelled culture media is old in the art. For example, the primary reference the Office cites, Merlino,

teaches the use of CHROMagar Staph aureus, which contains agar at 15 g/liter.

Merlino, page 2378, 2nd column. A culture medium containing agar at that concentration is a “gelled culture medium.” Therefore, an argument that recitation of a “gelled culture medium” is a basis to distinguish the references cited in the July 2007 Office action would fail. Applicants have not made that argument. The newly cited Bochner and Gosnell references, citing for their alleged teaching of gelled media, add nothing new of pertinence over the combined teachings of the references cited in the July 2007 Office action. Thus, Applicants’ claims are patentable over the teaching of Bochner or Gosnell in combination with Merlino, Felten, Boggs, Dorso, Hanaki, Rambach, Carricajo, and Pead (however combined) for the reasons set forth by Applicants in the Amendment filed January 10, 2008. Applicants respectfully request that the Office consider those arguments.

The relevance of the amendment of the composition claims to recite a “gelled culture medium” relates to a single argument and applies less to that language and more to the concurrently made amendment that the antibiotic in the gelled culture medium is “added to the medium before the medium gels.” For the Office’s convenience, that argument is reproduced here:

Furthermore, in response to Applicants’ arguments filed on April 30, 2007, the Office states:

Instant claim 1 only requires that the medium comprise an antibiotic. By the disk diffusion method, antibiotic is locally applied to medium by using small disks as a carrier. However it is understood that the antibiotic diffuses through the medium in a graded fashion. Therefore, by application of the disk diffusion method as taught by

Felten, for example, the medium does, in fact, contain antibiotic as required in instant claim 1.

Office Action, page 13.

As amended, claims 17-54 recite that the antibiotic is "added to the medium before the medium gels" The antibiotic, therefore, is not present in the medium in a graded fashion as occurs in the disk diffusion method taught by Felten. The conclusion that Felten teaches an antibiotic as required by claims 17-54 is incorrect.

Amendment filed January 10, 2008, page 20.

Respectfully, there was no need for the Office to search for and cite new art teaching the use of gelled culture media because that teaching was found in the references cited against the claims in the July 2007 Office action. Applicants have established the patentability of their claims over their references for all of the reasons presented in the January 2008 Amendment. Adding the Bochner or Gosnell references to the teachings of the reference of record is merely cumulative, adding nothing new upon which to find the claims unpatentable. Accordingly, Applicants request reconsideration and withdrawal of the rejection.

B. The Claims Are Patentable Over the References Cited in the Opposition Filed on Behalf of Biorad Pasteur Against European Patent No. 1 543 147, Further in View of U.S. Patent Nos. 5,989,853, 6,436,631, and 6,696,239 to Bochner, or U.S. Patent No. 6,130,057 to Gosnell

The Office also rejects claims 17-28, 31-34, and 36 under 35 U.S.C. § 103(a) as allegedly unpatentable "over the art of record as stated in the reference submitted in the IDS Jan 10, 2008 Becker & Associates OPPO023 GROUNDS FOR OPPOSITION ON BEHALF OF BIORAD PASTEUR, AGAINST EP 1 543 147 (ALAIN RAMBACH) [hereafter "Biorad Opposition"]," further in view of U.S. Patent Nos. 5,989,853,

6,436,631, or 6,696,239 to Bochner, or U.S. Patent No. 6,130,057 to Gosnell. Office action, page 4. Applicants traverse the rejection.

Applicants have reproduced in the preceding section the substance of the rejection and so will not repeat it here. The Biorad Opposition cites ten references. One of those references, Tande and Picard, was published in December 2003 and thus is not prior art which is the national stage of a PCT application filed on September 23, 2003, claiming benefit under 35 U.S.C. §119 to a French application filed September 23, 2002. To the extent the Office is relying collectively on the teachings of all of the references cited in the Biorad Opposition, this alone is sufficient to overcome the rejection.

But it is entirely unknown from the Office action whether the Office in making this rejection is relying on all of the references cited in the Biorad Opposition, or one or more combinations including some of the references. It is entirely unknown what teachings in the references the Office is relying on to find the claims are obvious and how those teachings apply to the pending claims. "In order to provide a complete application file history and to enhance the clarity of the prosecution history record, an examiner must provide clear explanations of all actions taken by the examiner during prosecution of an application." M.P.E.P. § 707.07(f); emphasis added. That has not happened here. The Office has not provided any explanation, much less a clear one, that provides Applicants an opportunity to explain why the claims are patentable over the combination of references and thus the rejection should be withdrawn. Nor does the rejection as currently presented provide Applicants with any basis to determine if one or more claim amendments would distinguish over the combined teaching of the references.

Respectfully, the Office must do more than identify a collection of references and assert claims would have been obvious to one of skill in the art over them:

Office personnel fulfill the critical role of factfinder when resolving the *Graham* inquiries. . . . **When making an obviousness rejection, Office personnel must therefore ensure that the written record includes findings of fact concerning the state of the art and the teachings of the references applied.** . . . Factual findings made by the Office are the necessary underpinnings to establish obviousness.

Once the findings of fact are articulated, **Office personnel must provide an explanation to support an obviousness rejection under 35 U.S.C. 103.** 35 U.S.C. 132 requires that the applicant be notified of the reasons for the rejection of the claim so that he or she can decide how best to proceed.

Examination Guidelines for Determining Obviousness Under 35 U.S.C. 103 in View of the Supreme Court Decision in *KSR International Co. v. Teleflex Inc.*, 72 Fed. Reg. 57526, 57527 (October 10, 2007); emphasis added.

The Office has not articulated any findings of fact. The Office has not provided an explanation supporting the rejection. Applicants, in the absence of any articulated facts or reasoning, are unable to decide how best to proceed. Applicants respectfully request that the Office withdraw the rejection, or alternatively, provide an explanation of the rejection so that Applicants may respond to it.

III. Conclusion

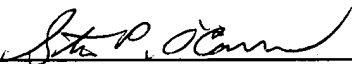
In view of these remarks, Applicants respectfully request reconsideration of the application and timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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